AUG 1 0 2001

K011484 Pg 1 of 2

SMDA 510(k) SUMMARY
OLYMPUS Injector

A. Submitter's Name, Address, Phone and Fax Numbers

1. Manufacturer of the subject devices

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjyuku Monolis Nishi-Shinjuku, Shinjyuku-ku Tokyo, Tokyo 163-0914 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 426-42-5177 FAX 426-46-5613

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Ms. Laura Storms-Tyler Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name:	Olympus Injector NM-4-1, NM-5-1, NM-6-1, NM-7-1, NM-8-1, NM-9-1
Common Name:	Injector
Classification:	Endoscope and accessories 21 CFR 876.1500
Predicate Device:	Olympus Disposable Injector NM-10L~17L (K902736 Sterile NM Injection Needle) Olympus Disposable Injector NM-21L (K984358 Distal Attachment, Component of EMR Kit)

D. Description of the Device(s)

Olympus Injector has been designed to be used with an Olympus endoscope to perform Endoscopic sclerotherapy, hemostasis, submucosal injection within the GI tract such as esophagus, stomach, duodenum, small intestine, large intestine.
This injector is consist of sheath section and needle section. The sheath section is non-sterile, reusable, and the needle section is sterile, disposable.

E. Intended Use of the Device(s)

Olympus Injector has been designed to be used with an Olympus endoscope to perform following therapy.

1) Endoscopic sclerotherapy within the esophagus, stomach, duodenum, large intestine.
2) Endoscopic hemostasis within the esophagus, stomach, duodenum, small intestine, large intestine.
3) Endoscopic submucosal injection within esophagus, stomach, duodenum, small intestine, large intestine.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, the Olympus Injector does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

Olympus Optical Co., Ltd.
% Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K011484
Olympus Injector NM-4-1, NM-5-1, NM-6-1,NM-7-1,
NM-8-1, NM-9-1, NM-4U-1, NM-4Z-1
Dated: May 10, 2001
Received: May 14, 2001
Regulatory Class: II
21 CFR 876.1500/Procode: 78 FBK
21 CFR 878.4800/Procode: 79 GAA

Dear Ms. Storm-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (special Controls) or class III (premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as Set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 592-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 592-4639. Also, please note the regulation entitled, "Misbranding by reference notification" (21CFR 807.97). Othr general information on your responsibilities under the Act may be obtained from the Division of Small Manufactures International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address http://www.da.gov/cdrh/dsma/dsmamain.html.

Sincerely Yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known): K011484

Device Name: Olympus Injector NM-4-1, NM-5-1, NM-6-1, NM-7-1, NM-8-1, NM-9-1

Indications for Use:

Olympus Injector has been designed to be used with an Olympus endoscope to perform following therapy.

1) Endoscopic sclerotherapy within the esophagus, stomach, duodenum, large intestine.
2) Endoscopic hemostasis within the esophagus, stomach, duodenum, small intestine, large intestine.
3) Endoscopic submucosal injection within esophagus, stomach, duodenum, small intestine, large intestine.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR _____
Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011484